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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/521,524 03/08/00 DAVIDSON

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021186 HM12/0705
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EXAMINER

FOLEY, S

ART UNIT

PAPER NUMBER

1648

DATE MAILED:

07/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/521,524

Applicant(s)

DAVIDSON ET AL.

Examiner

Shanon A. Foley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-8 and 10-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-8 and 10-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

In the amendment filed 4/20/01, applicant cancelled claims 1 and 9 and added new claim 26. Claims 2-8, 10-26 are under consideration.

Response to Arguments

Applicant's arguments filed 4/20/01 in paper no. 7 have been fully considered but they are not persuasive.

Claim Objections

NO
2
Claims 2-8 and 10 are objected to because of the following informalities: these claims are dependent from independent claim, 16. It should be kept in mind that a dependent claim must refer to any preceding independent claim. See MPEP § 608.01(n). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

NO
2
The claim is drawn to an article of manufacture comprising packaging material and a cloning system. There is no component within the "article of manufacture" that is distinguishable from the "cloning system" in the previous claims. A kit with identical reagents and a detailed protocol is taught or suggested by references such as Aoki et al. Copyright law controls the

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packaging material containing the printed content of the detailed protocol, and the printed

content is not patentable.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-8, 10-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The amendment filed 4/16/01 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: claims 2-8, 10-26 recite that the plasmid lacks a loxP sequence. This negative limitation cannot be found in the original disclosure. The courts have found that any negative limitation or exclusionary proviso must have basis in the original disclosure. The mere absence of a positive recitation is not basis for an exclusion. See *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984). In addition, claim 26, applicant states that support can be found for the new claim on page 4, lines 7-9, and page 6, line 26-page 7, line 8. The examiner is unable to find support for "an article of manufacture" or the equivalent.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 4-6, 10, 11, 13-19, and 22-26 are rejected under 35 U.S.C. 102(a) as being anticipated by Aoki et al.

NO
New claim 26 is anticipated by the teachings of Aoki et al. because the components of the article of manufacture are indistinguishable from the components of the cloning system taught by Aoki et al.

Applicant has responded to the Office action and stated that the 102 rejection by Aoki et al. was under 35 U.S.C. 102(b). Applicant should note that the rejection was under 35 U.S.C. 102(a).

Applicant argues that Aoki et al. does not anticipate the claims, as amended, because the reference does not teach a cloning system that lacks a loxP sequence.

As stated above, there is no support for the newly added negative limitation in the specification. In addition, the claims are not limited to the elements specifically recited because the independent claims recite the language “comprising”. Therefore, the teachings of Aoki et al. anticipate claims 4-6, 10, 11, 13-19, and 22-26.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 3, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aoki et al. as applied to claims 4-6, 10, 11, 13-19, and 22-26 above, and further in view of Krougliak et al.

Applicant argues that should one skilled in the art combine the teachings of Aoki et al. and Krougliak et al., one would develop a full-length adenovirus because the adenovirus used by Krougliak et al. has a full viral backbone that includes a left-hand ITR.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Response to specific arguments regarding the teachings of Aoki et al. is stated above.

The claims rejected under Krougliak et al. in view of Aoki et al. are drawn to an adenovirus backbone plasmid lacking E4 and a cell line that expresses E1, E4, and pIX sequences. Aoki et al. teaches all of the limitations within the independent claims regarding specific map units deleted, along with the left-hand ITR of the adenovirus backbone in the adenovirus plasmids and Krougliak et al. teaches modification of E4 and generation of a helper cell line that expresses E1, E4, and pIX. One of ordinary skill in the art at the time the invention was made would have been motivated to combine the adenovirus system taught by Aoki et al. with the teachings of Krougliak et al. if one wanted to express a large piece of foreign DNA into the an adenovirus recombinants taught by Aoki et al. Therefore, the teachings of Aoki et al. in

further view of Krougliak et al. render the claims obvious to one skilled in the art at the time the invention was made.

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aoki et al. and Krougliak et al. as applied to claims 2-6, 10, 11, 13-26 above, and in further view of Breakfield et al.

Applicant argues that the teachings of Breakfield et al. do not render the invention obvious, in further view of Aoki et al. and Krougliak et al. Applicant argues the references independently and states that Breakfield et al. does not teach an adenovirus vector. Applicant further repeats that the claims are directed to adenovirus plasmids that lack loxP sequences and the left-hand ITR.

In response, it was stated in the previous rejection in the last paragraph on page 6 that Breakfield et al. does not teach specifically teach adenovirus shuttle vectors. That was why the reference was combined with the teachings of Aoki et al. and Krougliak et al. One of ordinary skill in the art at the time the invention was made would have immediately recognized the analogous genomes of AAV used in the teachings of Breakfield et al. and applied the teachings to the adenovirus shuttle vector taught by Aoki et al. Therefore, the teachings of Aoki et al., Krougliak et al., and Breakfield et al. render claims 4-8, 10, 11, 13-26 obvious to one of ordinary skill in the art at the time the invention was made.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aoki et al., Krougliak et al., and Breakfield et al. as applied to claims 4-8, 10, 11, 13-26 above, and further in view of Chartier et al.

Applicant states that the teachings of Chartier et al. do not remedy the deficiencies noted before in previous arguments to the references.

Applicant's arguments directed to deficiencies in the references are not persuasive, see the response to the arguments above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon A. Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on 7:30-4:30 M-F.

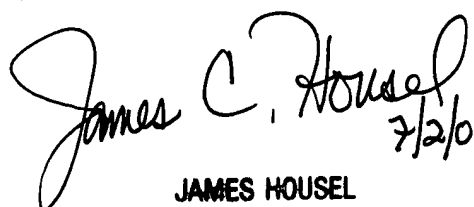
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the

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organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley
June 20, 2001


7/2/01
JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600